

NCIB Meeting – 31 May 2012

Standards Enabling the Conduct of Clinical Research

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Strength through Collaboration



We should make sure we are using the information wisely, that it is accurate and we can find it.... We owe it to the patients who agree to participate in research studies and share their data.

“One has to simply examine the phenomenon taking place in the various ‘PatientsLikeMe’ web-based communities to gain a glimpse of what a world of shared patient data looks like. Daily entries by tens of thousands of individuals indicate the drive some people possess for sharing data with others.”

Terry, S.F., Terry, P.F. “Power to the People: Participant Ownership of Clinical Trial Data” Science Translational Medicine, Feb 2011

Desired Qualities for Standards to Enable Clinical Research

- Global, open and free
- Developed through recognized standards development process
- Collaborative and cooperative; consensus-based
 - not proprietary, 'one-off' or redundant
- Harmonized and semantically consistent
- Support interoperability with healthcare

Existing Standards Enabling the Conduct of Clinical Research

- BRIDG (Biomedical Research Integrated Domain Group) Model
- CDISC Suite of Standards focused on supporting medical research, from protocol through analysis and reporting
- Controlled Terminology for the above, curated in EVS Thesaurus/Metathesaurus
- Therapeutic Area Standard for Alzheimer's, Parkinson's Disease, Pain, TB, etc.
- IHE Integration Profiles (RFD, RPE) and HL7 EHRCCR Functional Profile
- Interoperability Specification # 158 (HITSP) to support collection of a core set of standard research data from electronic health records

BRIDG

- **BRIDG Purpose:**

A collaborative effort to produce a shared view of the dynamic and static semantics that collectively define a shared domain-of-interest.

- The semantic foundation for HL7/CDISC-based application and message development
- Harmonizes the CDISC standards and other similar standards

- **Domain-of-interest/scope: Protocol-driven research**

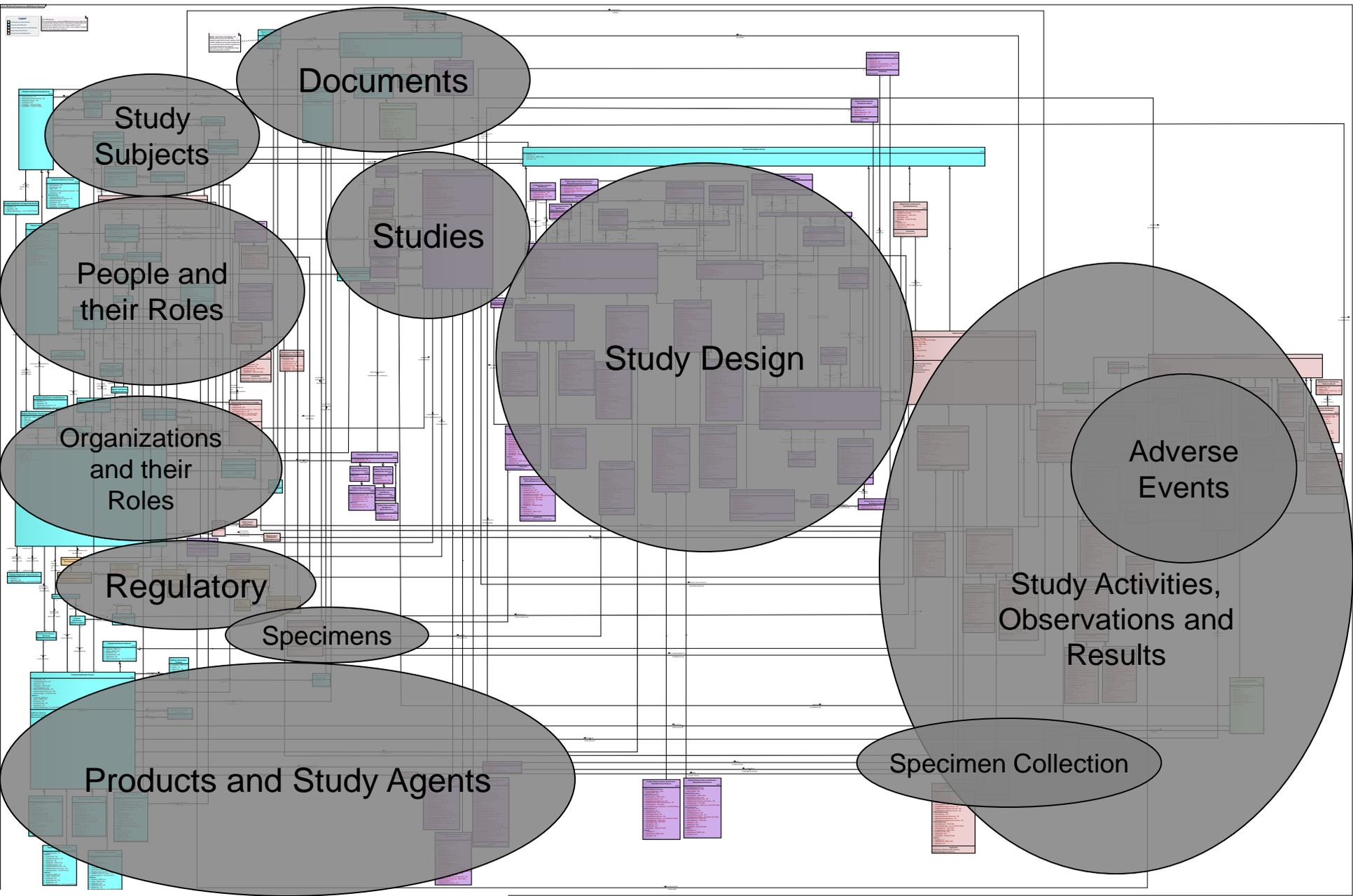
- **Core Stakeholders:**    

- **Governance Process:**

Board of Directors prioritizes projects and committee consults with projects and harmonizes project models into main model with help of project analysts/SMEs

- **On the path to becoming an ISO/CEN Standard through JIC**

BRIDG Model Content



Domain-Friendly, Subdomain-Specific Business Models

Layer 1

SME View



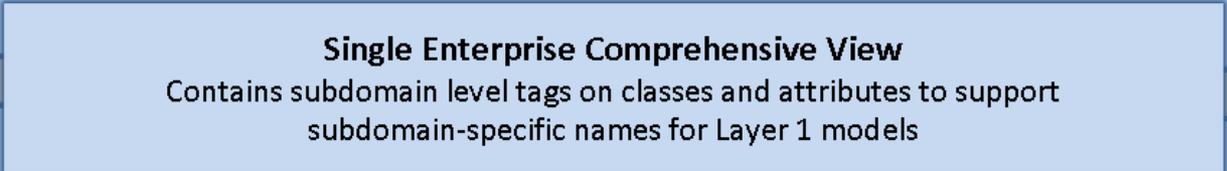
Separate EA/XMI file for each subdomain

Transformer

BRIDG Domain Analysis Model (DAM)

Layer 2

Canonical View



Single EA file with comprehensive and subdomain Views



Manual Mapping

OWL View

RIM-Based BRIDG Model

Layer 3

HL7 RIM View



Equivalent to an HL7 DMIM (HL7 Visio)



- Global, open, multi-disciplinary, vendor-neutral, non-profit (501c3) standards developing organization (SDO)
- Founded 1997, incorporated 2000
- Supported partially through memberships (~300 org. members, e.g. academia, biopharma, service / technology providers); also grants, education and contributions
- Liaison A Status with ISO TC 215
- Leadership of Joint Initiative Council (JIC) for Global Harmonization of Standards
- Charter agreement with HL7 (2001)
- Member of ANSI-led ISO TAG
- Leader of IHE QRPH Committee
- Active Coordinating Committees (3C)
 - Europe, Japan, China, Korea
- 20 User Networks (includes 10 in US + S. Africa)
- >> 60 countries in participant database

Clinical Data Interchange Standards Consortium

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CDISC Strength Through Collaboration

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CDISC Interchange, North America
9 - 13 November 2009 | Baltimore

Interchange North America

What's New

CDISC Group Rate for the Interchange Hotel Closes 26 October 2009
Hotel Booking Extended! Don't Delay, Book Today!

North America Interchange Registration Open!
Register now!

CDISC Shared Health and Clinical Research Electronic Library (SHARE) Webinar
Missed the webinar? View it online now!

CDISC Announces Public Training in China
26 - 30 October 2009
Beijing
China

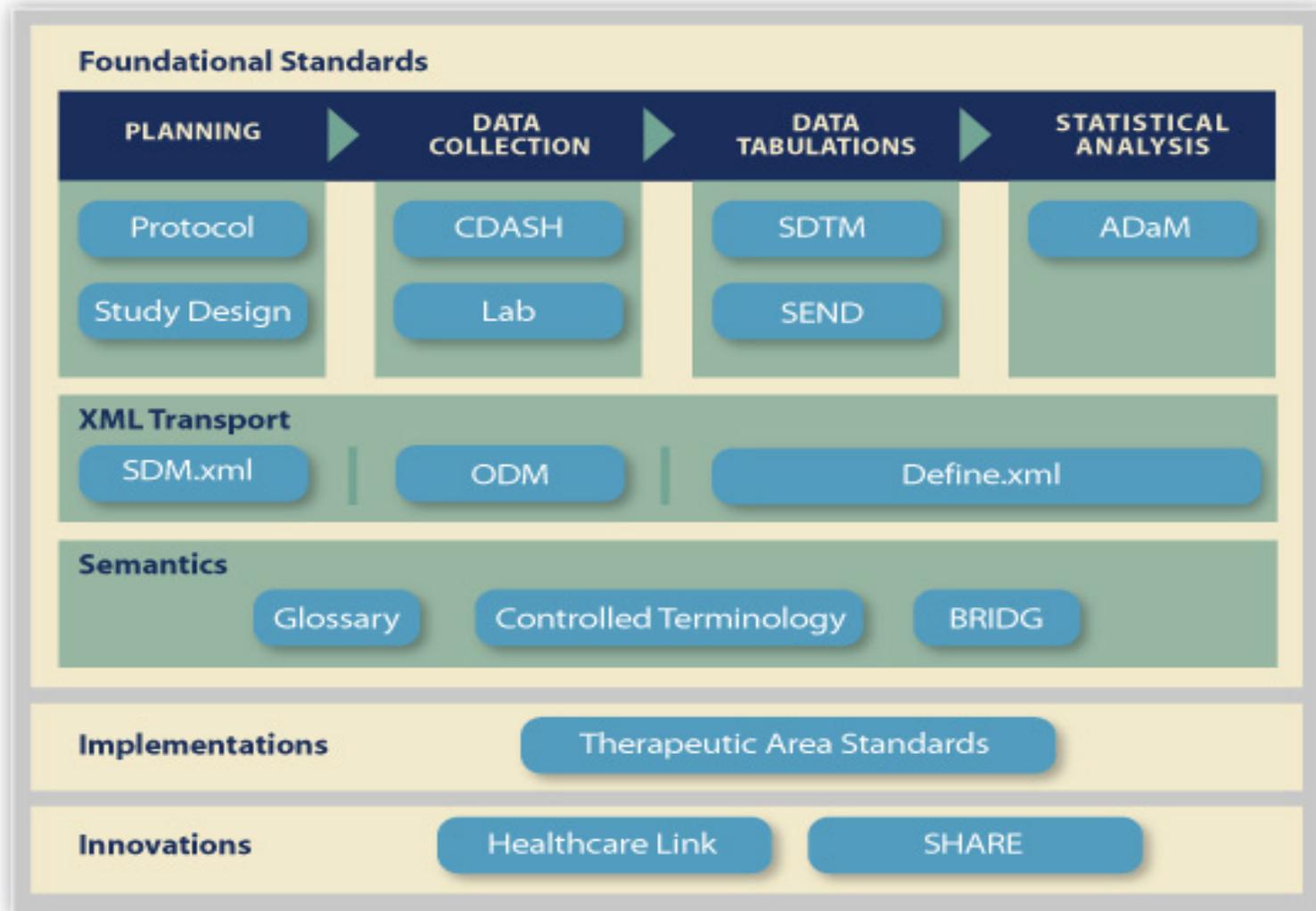
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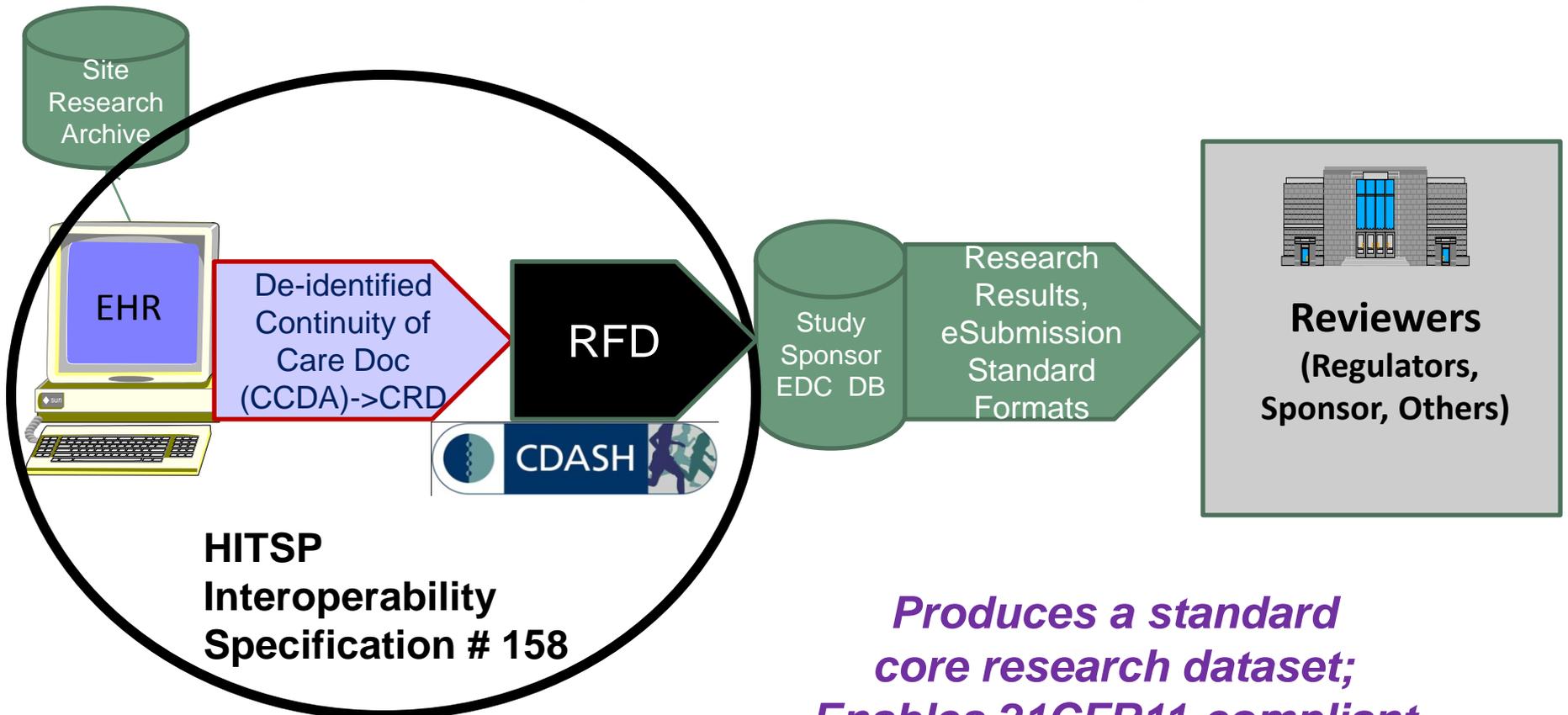
The 'common language' for global clinical research

CDISC Global Standards for Protocol-Driven Clinical Research



Consensus-based, open and freely available – www.cdisc.org

Patient Value: Quality of Healthcare, Safety



**HITSP
Interoperability
Specification # 158**

*Produces a standard
core research dataset;
Enables 21CFR11-compliant
interoperability and eSource*

NCI – Current Roles/Contributions

- NCI should be commended for leadership, accomplishments and expertise in this area, particularly services for controlled Terminology/EVS and CDEs
- Key Stakeholder in BRIDG, providing expertise and resources
- LSDAM – Life Sciences Domain Analysis Model now being ‘integrated’ with BRIDG
- Alignment of CDASH and analogous NCI CDEs
- TA Standards development with CDISC and HL7 CIC
- Much more...

Standards and 'Tools' Needed

- A global, accessible electronic library, which through advanced technology, enables precise and standardised data element definitions (including value sets) that can be used in applications and studies to improve biomedical research and its link with healthcare (e.g. SHARE = Shared Health and Research Electronic Library)

Key purposes:

- a) Develop therapeutic area standards & others faster*
- b) Make current standards more accessible and useful*

- Therapeutic area standards (e.g. for oncology studies worldwide) offered through an SDO

Suggestions for NCIB-Discussion

- Use relevant and appropriate existing standards and promote these throughout NCI
- Develop specific, meaningful data sharing plans
- Base NCI standards plan/roadmap on BRIDG
- Collaborate to develop **global** oncology-specific standards
- Invest in a new open SI environment with BRIDG/EVS as core infrastructure
- Inform Meaningful Use 3

*** Continue to collaborate with SDOs and others:

Innovative Medicines Initiative (IMI)

NLM and/or NCATS

EORTC

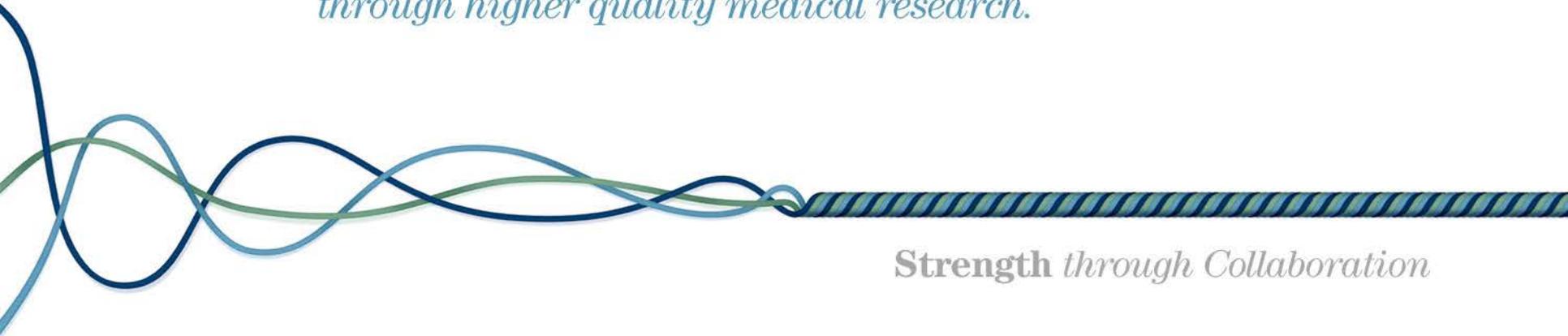
CIMI

Patient Groups and Others...



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

*The CDISC vision is to inform patient care & safety
through higher quality medical research.*

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Strength *through Collaboration*